

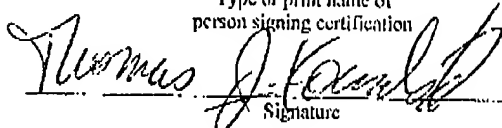
PATENT
830010-2002.2#17
MP
11/18/03**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s) : Pasternak et al.
Serial No. : 09/975,812
For : TOPICAL ANESTHETIC/OPIOID
FORMULATIONS AND USES THEREOF
Filed : October 11, 2001
Examiner : M. Bahar
Art Unit : 1617

745 Fifth Avenue
New York, NY 10151**FACSIMILE**

I hereby certify that this paper is being facsimile transmitted to the
Patent and Trademark Office on the date shown below.

Thomas J. Kowalski, Reg. No. 32, 147

Type or print name of
person signing certification
Signature

November 3, 2003

Date of Signature

DECLARATION OF GAVRIL PASTERNAK UNDER 37 C.F.R. §1.132

Mail Stop Non Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Gavril Pasternak, hereby declare as follows:

1. I am a citizen of the United States of America and a named inventor in the above-identified application. I respectfully submit that I am qualified to speak and render opinions as to the disclosure in the present application and the state of the art, as I am considered an expert in the field and have familiarity with the present application and its prosecution. I either

PATENT
830010-2002.2

performed, supervised or controlled any experimental work reported in the present application, in the ordinary course of business.

2. In accordance with the experimental protocol carried out in Example 2, the individual dosage forms of morphine and lidocaine administered topically to subjects in combination were:

	Morphine Dosage	Lidocaine Dosage
Set #1	1.5 mM morphine	0.22 mM lidocaine
	1.5 mM morphine	0.45 mM lidocaine
	1.5 mM morphine	0.9 mM lidocaine
	1.5 mM morphine	1.8 mM lidocaine
Set #2	3.0 mM morphine	0.45 mM lidocaine
	3.0 mM morphine	0.9 mM lidocaine
	3.0 mM morphine	1.8 mM lidocaine
Set #3	4.5 mM morphine	0.22 mM lidocaine
	4.5 mM morphine	0.45 mM lidocaine
	4.5 mM morphine	0.9 mM lidocaine
Set #4	0.4 mM morphine	0.45 mM lidocaine
	0.75 mM morphine	0.45 mM lidocaine
	1.5 mM morphine	0.45 mM lidocaine
	3.0 mM morphine	0.45 mM lidocaine
	6.0 mM morphine	0.45 mM lidocaine
Set #5	0.75 mM morphine	0.9 mM lidocaine
	1.5 mM morphine	0.9 mM lidocaine
	3.0 mM morphine	0.9 mM lidocaine
	4.5 mM morphine	0.9 mM lidocaine
Set #6	0.75 mM morphine	1.8 mM lidocaine
	1.5 mM morphine	1.8 mM lidocaine
	3.0 mM morphine	1.8 mM lidocaine
	4.5 mM morphine	1.8 mM lidocaine

3. Each set was used to calculate the ED₅₀ of either morphine or lidocaine at the specified fixed dose of the other.

NOV-10-03 MON 04:44 PM

FAX NO.

P. 11

NOV-3-2003 18:27 FROM: LAB MOLECULAR NEURO 212-794-4332

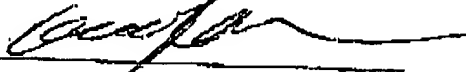
TO: 912125888500

P: 4/4

PATENT
830010-2002.2

4. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

11/03/03
Date


Gavril Pasternak, M.D., Ph.D.

11/03/03 18:51:44

USPTO->

RightFAX

Page 001

TO:Auto-reply fax to 12125880500 COMPANY:

Auto-Reply Facsimile Transmission



UNITED STATES
PATENT AND
TRADEMARK OFFICE

TO:

Fax Sender at 12125880500

Fax Information

Date Received:

11/3/03 5:42:38 PM [Eastern Standard Time]

Total Pages:

11 (including cover page)

ADVISORY: This is an automatically generated return receipt confirmation of the facsimile transmission received by the Office. Please check to make sure that the number of pages listed as received in Total Pages above matches what was intended to be sent. Applicants are advised to retain this receipt in the unlikely event that proof of this facsimile transmission is necessary. Applicants are also advised to use the certificate of facsimile transmission procedures set forth in 37 CFR 1.8(a) and (b), 37 CFR 1.6(f). Trademark Applicants, also see the Trademark Manual of Examining Procedure (TMEP) section 306 et seq.

Received
Cover
Page
=====>

11/04/2003 17:41 FAX 12125880500 FROM: FROMMER LAWRENCE & HAUG	
FROMMER LAWRENCE & HAUG LLP 745 Fifth Avenue New York, New York 10151 Telephone: (212) 589-0800 Facsimile: (212) 589-0508 E-mail: Firm@flhny.com	
FACSIMILE COVER LETTER	
To:	Examiner M. Bahar
From:	U.S.P.T.O.
Facsimile:	703/872-9306
From:	Amy Leahy, Ph.D.
Date:	November 3, 2003
Re:	Our Ref: E30010-2002.2
Number of Pages:	10
(including cover page)	
If you do not receive all pages or are unable to read the transmission, please call (212) 359 0800.	
CONFIDENTIALITY NOTICE	
<small>The documents accompanying this communication contain confidential information intended for a specific individual and purpose. The information is yours and is regulated by law. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or the taking of any action in reliance on the contents of this document is strictly prohibited.</small>	
001344X	

11/03/03 4:36:07 PM
 RECEIVED
 FROMMER LAWRENCE & HAUG LLP